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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/627,271

07/25/2003

Earl A. Hubbell

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22886

7590

10/27/2006

AFFYMETRIX, INC

ATTN: CHIEF IP COUNSEL, LEGAL DEPT.

3420 CENTRAL EXPRESSWAY

SANTA CLARA, CA 95051

EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,271	Applicant(s) HUBBELL, EARL A.	
	Examiner Pablo Whaley	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-14 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-14 and 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/16/2004 and 07/25/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

APPLICANT'S ELECTION

Applicant's election without traverse of Claims 4-14 and 25-33 (Group II) and Species (i), directed to oligonucleotides, in the reply filed on 08/25/2006 is acknowledged. Furthermore, the Examiner acknowledges that claims 1-3, 15-24, and 34-40 were canceled by the applicant in the preliminary amendment, filed 07/25/2003. Therefore claims 4-14 and 25-33 are currently pending.

CLAIMS UNDER EXAMINATION

An action on the merits of claims 4-14 and 25-33 (Group II) as they read upon the elected specie of polymer directed to oligonucleotides follows.

PRIORITY

Priority to US Applications 60/149,510, filed 8/17/99, and 60/182,288, filed 2/14/00, has been acknowledged. Priority to the Divisional Application, 09/640,962, filed 8/16/00, has been acknowledged.

OBJECTIONS

The Specification is objected to because of the following informalities: In the amendment, filed 07/25/2003, there is a typo, which needs to be corrected. See line 6. The application number should be 60/149,510, as it is stated previously. Appropriate correction is required.

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INFORMATION DISCLOSURE STATEMENT

The information disclosure statements filed 04/16/2004 and 07/25/2003 have been considered in full.

DRAWINGS

Drawings filed 7/25/2003 are acceptable.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-14 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 4-14 are directed to a computer implemented method for arranging polymers, which does not recite either a physical transformation of matter nor a practical application. Claim 4 recites computer-implemented steps generally directed to reducing edge count, dividing polymers into blocks, selecting blocks, and assigning blocks to empty slots. As these method steps may be achieved *in-silico*, and as the specification does not define these steps such that they are physical method steps (i.e. done by a user), the instant claims do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a concrete, tangible, and useful result (i.e. a practical application). While claim 4 results in "assigning one block...to an empty slot, wherein said one block results "a least edge count", it is emphasized that no

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information regarding the arrangement of polymers is "output" to a user. Therefore, no tangible result is communicated to a user such that it is useful to one skilled in the art. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-14 and 25-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 and 25 recite the limitation "...for combinatorial synthesis of said polymers on a substrate" in the preamble. It is unclear if said "substrate" is directed to an intended use of the instant method, or is required by the instant method. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claim 4 and 25 recite the limitation "reducing edge count between polymers. " The specification does provide a limiting definition of the term "edge count" [p.12]. Therefore, it is unclear as to the intended meaning of "edge count" such that one skilled in the art would know in what way said "edge count" is reduced "between polymers." Clarification is requested. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claim 4 and 25 recite the limitation "wherein each of said block...comprising...polymers" (lines 4-5). It is unclear in what way this limitation further limits the instant method. Furthermore, there is lack of antecedent basis for "said block." It is noted that claim 4 previously recites a "plurality of blocks." Correction is required.

Claim 4 and 25 recite the limitation "wherein each of said blocks is to be assigned to one slot on said substrate" (line 5). It is unclear if this is intended to be an active method step, a further limitation of said "blocks", or something else. If applicant intends for this to be an active method step, the claim language should clearly reflect this intension. Clarification is requested. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claim 4 and 25 recite the limitation "in said set" (line 8). There is lack of antecedent basis for "said set." It is noted that claim 4 previously recites a "selecting a subset." Correction is required.

Claim 4 and 25 recite the limitation "selecting...from unassigned blocks" (line 7). As no step directed to "assigning" was previously recited, it is unclear in what way one of skill in the art would be able to selected from "unassigned blocks." Clarification is requested.

Claim 4 and 25 recite the limitation "assigning one block...to an empty slot, wherein said one block is the best fitting and results in a least edge count..." (lines 8-9). It is unclear in what way "assigning one block" results in a "least edge count." Clarification is requested.

Claim 4 and 25 recite the limitation "an empty slot" (line 8). There is lack of antecedent basis for this limitation. It is noted that claim 4 previously recites "one slot on a substrate." Correction is required.

Claim 4 and 25 recite the limitation "the best fitting" (line 9). There is lack of antecedent basis for this limitation. Furthermore, it is unclear as to the intended meaning of "best fitting" in this context. Correction is required.

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Claim 6 recites the limitation "each of said edge counts represents the result of assigning one block to an empty slot". It is unclear in what way said edge counts "represent the result of assigning." Clarification is requested. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claim 7 recites the limitation "the first subset among unassigned blocks." There is lack of antecedent basis this limitation. Correction is required.

Claims 8-10 and 29-31 recite the limitation "the last of said subsets." It is unclear whether applicant is referring to a subset of assigned or unassigned blocks. Clarification is requested.

Claims 8-10 and 29-31 recite the limitation "other subset." There is lack of antecedent basis this limitation. Furthermore, it is unclear what "other" subset applicant is referring to. Correction is required.

Claim 11 recites the limitation "said combinatorial synthesis is radiation directed synthesis." It is unclear in what way this limitation further limits the claimed method. It is noted that parent claim 4 recites "for combinatorial synthesis" in the preamble, but there is no active method step directed to combinatorial synthesis per se. Correction is required.

Claim 33 recites the limitation "weighted edge count taking into account distance to cell leaking radiation." It is unclear as to the intended meaning of "taking into account" such that one skilled in the art would know in what way a weighted edge count "takes into account" distance. Clarification is requested. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claims 4-14 and 25-33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 4 and 25 recite the limitation "reducing edge count" (line 3). The

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omitted essential step appears to be generally directed to obtaining an "edge count."

Clarification is requested.

Claim 4 and 25 recite the limitation "wherein said one block is the best fitting and results in a least edge count..." (line 9). The omitted essential step appears to be generally directed to minimization of a block and/or an edge (i.e. obtaining a "best fitting" block, or "least edge count"). Clarification is requested. Claims 5-15 and 26-32 are also rejected as they depend from rejected claims 4 and 25.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 5, 7-13 are rejected under 35 U.S.C. 102 (b) as being unpatentable over Pease et al. (Proc. Natl. Acad. Sci., May 1994, Vol. 91, p.5022-5026).

Pease et al. teach a method for arranging oligonucleotides on DNA chips for parallel DNA analysis [Abstract]. More specifically, Pease et al. teach the following aspects of the instant invention:

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- Light-directed (i.e. radiation) combinatorial synthesis of oligonucleotides using masks [p.5025, Col. 1, ¶ 2], wherein each “round” results in a reduced distance between edges between oligonucleotides [Fig. 4], which equates to “reducing edge count” as in claims 4, 11, 12, and 13.
- Lithographic subdivision of oligonucleotides into a plurality of blocks on a substrate [Fig. 4], which equates to “dividing” as in claim 4.
- Iterative selection and activation of blocks for coupling oligonucleotides to empty blocks in the substrate [Fig. 4], which equates to “assigning” to unassigned blocks as in claims 4 and 7. Furthermore, a maximum of 256 blocks are generated [Fig. 4] and can be expanded to 65,536 blocks [p.5025, Discussion], therefore claims 8-10 are also anticipated.
- Repeating above steps until the desired set of products is obtained [p.5022, Col. 2, ¶4], as in claim 5.

Claims 4-6 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (Genomics, 1997, Vol. 40, p.476–485).

Li et al. teach an automated software package, PRIMO, for designing PCR primer pairs using quality information associated with each base call (abstract). More specifically, Li et al. teach the following aspects of their software program that anticipate the instantly claimed invention:

- Trial and accepted oligonucleotide primers [p.483, Col. 1, ¶ 1], which equates to assigned and unassigned blocks, as in claims 4 and 25.

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- Reducing the gap between primer pairs via clipping [p.481, Col. 2, ¶ 1], which equates to “reducing edge count” as in claims 4 and 25.
- Dividing oligonucleotide primers into a plurality of regions (i.e. blocks), and selecting regions with sufficient quality [Fig. 1], as in claims 4 and 25.
- Computing and comparing BQ scores to a threshold for determining appropriate bases for assigning bases for primer design [p.478, Col. 2, ¶ 2] and [Table 2], as in claims 4, 6, 25, and 27.
- Repeating methods assigning until appropriate primers are found [Fig. 3], as in claims 5 and 26.
- Code written in ANSI C and maintained in two versions for use with MAC and UNIX processors (Abstract), as in instant claim 25.

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner
Art Unit 1631
Office: 571-272-4425

Lois A. Claw
Patent Examiner
10/24/06